DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

April 21, 2015

Medela Ag
% Adrienne Lenz
Member
Pathway Regulatory Consulting, LLC
W324 S3649 County Road E
Dousman, WI 53118

Re: K150499
Trade/Device Name: Freestyle Deluxe, Freestyle Solution Set, Freestyle Basic, Freestyle Motor Warranty
Regulation Number: 21 CFR 884.5160
Regulation Name: Powered Breast Pump
Regulatory Class: II
Product Code: HGX
Dated: February 23, 2015
Received: February 26, 2015

Dear Adrienne Lenz,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR

Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Herbert P. Lerner -S

for Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K150499

Device Name
Freestyle®

Indications for Use *(Describe)*
The Freestyle® is a powered breastpump to be used by lactating women to express and collect milk from their breasts. The Freestyle® is intended for a single user.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(K) SUMMARY

Medela AG
Freestyle® double electric breast pump

510(k) Summary

K150499

In accordance with 21 CFR 807.92 the following summary of information is provided:

DATE: April 20, 2015

SUBMITTER:

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SECONDARY CONTACT PERSON:

Orlando Antunes
Vice President Regulatory Affairs
Medela AG

DEVICE:

TRADE NAME: Freestyle®

COMMON/USUAL NAME: Double electric breastpump

CLASSIFICATION NAMES: 884.5160 Powered breast pump

PRODUCT CODE: HGX

PREDICATE DEVICE(S):

Lansinoh powered electric breast pump (K122474)

Medela AG
Freestyle® double electric breast pump

DEVICE DESCRIPTION:

The Medela Freestyle® double electric breastpump system is comprised of the Freestyle® pump (motor unit), the Freestyle® media separation pump kit including tubing, the rechargeable battery, the AC/DC power supply and soft good accessories (tote bag, cooler bag with ice pack). The Medela Freestyle® pump is a double electric breastpump for pumping breastmilk from a single breast or simultaneously from both breasts of a lactating woman by applying a cyclic negative pressure.

The Freestyle® double electric breastpump is a mobile, personal, medical device that includes Medela's 2-Phase Expression technology and is intended to be used by a single user in a closed space as for example a home or office environment.

The Medela Freestyle® double electric breastpump is AC/DC powered and incorporates a DC-motor with membrane aggregate in its pump motor unit. A user friendly display offers information as for example duration of pump session or set vacuum level. The Freestyle® double electric breastpump is mobile and can be operated by connecting to the power supply and / or by rechargeable battery. The connection port for the power supply is located at the bottom side of the pump unit. The battery compartment is at the back of the pump motor unit and is covered by a battery door. The runtime of the removable lithium-ion battery is influenced by the number and duration of pumping sessions and lasts usually for one day. When the Freestyle® pump motor unit is connected to the power supply, the battery is recharged automatically.

A variety of accessories are available for use with the Freestyle® or are intended to be marketed with these pumps.

INDICATIONS FOR USE:

The Freestyle® is a powered breastpump to be used by lactating women to express and collect milk from their breasts. The Freestyle® is intended for a single user.

DETERMINATION OF SUBSTANTIAL EQUIVALENCE:

SUMMARY OF TECHNOLOGICAL CHARACTERISTICS OF THE DEVICE COMPARED TO THE PREDICATE DEVICE

The Freestyle® double electric breastpump uses the same fundamental technology as the Lansinoh powered electric breast pump (K122474). Its 2-phase expression technology is the same as used in other Medela breast pumps, including the Medela Symphony (K020518).

The table below summarizes the key specifications of the Freestyle® and the predicate devices.

Medela AG
Freestyle® double electric breast pump

Device name	**Freestyle® Breastpump**	**Lansinoh powered electric breast pump, now marketed as Lansinoh Affinity Pro (K122474)**	**Discussion**
Indications for Use	The Freestyle® is a powered breastpump to be used by lactating women to express and collect milk from their breasts. The Freestyle® is intended for a single user.	The Powered Breast Pump is intended to express and collect the breast milk of a nursing woman for the purpose of feeding the collected milk to a baby. The Powered Breast Pump is intended for a single user.	Equivalent. Both devices express and collect milk. Both devices are intended for a single user.
Intended Use	Express and collect milk	Express and collect milk	Identical
Single user device	Yes	Yes	Identical
Environment of Use	Home	Home	Identical
User Interface	Hardware interfaces	Hardware interfaces	
User Control	On-off switch Vacuum/Cycle-adjustment control	On-off switch Vacuum-adjustment control Cycle-adjustment control	Equivalent – Affinity Pro has two independent controls for vacuum and cycles. Freestyle's® uses a single control to adjust vacuum and cycles together. Freestyle's® controls are the same as reference Symphony (K020518).
Visual Indicator	LCD display	LCD display	Equivalent
Pumping Options	Single or Double	Single or Double	Equivalent
Accessories	A variety of accessories for: • Collection of milk • Storage of milk • Breast care • Providing Power • Carrying • Cleaning • Feeding	A variety of accessories for: • Collection of milk • Storage of milk • Breast care • Providing Power • Carrying	Equivalent – both systems come with or make available a variety of accessories that can be used with the pump for collection and storage of breast milk, providing power, carrying and breast pump. Freestyle® has additional accessories for cleaning its components and feeding stored milk.
Media Separation	Yes	Yes	Equivalent

Medela AG
Freestyle® double electric breast pump

Device name	**Freestyle® Breastpump**	**Lansinoh powered electric breast pump, now marketed as Lansinoh Affinity Pro (K122474)**	**Discussion**
Specifications			
Power Supply	• Li-Ion battery or • AC adaptor provided	• 6 AA batteries or • AC adaptor provided	Equivalent
Suction Levels (stimulation)	40 - 140 mmHg	55 - 140 mmHg	Equivalent – vacuum levels are user adjustable, with Freestyle® having the ability to pump at a lower vacuum
Cycles per Second (stimulation)	1.7-1.93	1.55 – 2.4	Equivalent
Suction Levels (expression)	45 – 245 mmHg	80 -220 mmHg	Equivalent – vacuum levels are user adjustable, with Freestyle® having the ability to pump at a lower vacuum
Cycles per Section (Expression)	0.83-1.36	0.61-1.52	Equivalent
Maximum vacuum	270 mmHg	Not available	Equivalent
Suction Settings	9	8	Equivalent
Adjustable Suction Levels	Yes	Yes	Identical
Let-Down Button	Yes	Yes	Identical
Cycling Control Mechanism	Microcontroller	Microcontroller	Equivalent
Back Flow Protection	Yes	Yes	Equivalent

Device name	**Freestyle® Breastpump**	**Lansinoh powered electric breast pump, now marketed as Lansinoh Affinity Pro (K122474)**	**Discussion**
2-phase expression	Yes	Yes	Equivalent. Both devices offer an initial simulation phase that moves to expression phase after two minutes. Freestyle's® 2-phase expression technology is also equivalent to reference device Symphony (K020518). Refer to **Exhibit 12.1** for additional discussion.

SUMMARY OF NON-CLINICAL TESTS:

The Freestyle® double electric breast pump complies with voluntary standards for electrical safety, electromagnetic compatibility, use in the home healthcare environment and powered suction pumps. The following quality assurance measures were applied to the development of the system:

- Risk Analysis
- Cleaning Validation
- Biocompatibility Evaluation
- Software Validation
- Electrical safety and electromagnetic compatibility testing per IEC 60601-1 and IEC 60601-1-2 standards, respectively
- Safety testing for use in the home per IEC 60601-1-11 standard
- Usability evaluation and validation.
- Performance testing demonstrating compliance with EN ISO 10079-1: 2009 Particular requirements for the safety of electrically powered suction equipment
- Performance Testing to determine the vacuum performance, including minimum and maximum vacuum levels for the pump as compared to the predicate device, vacuum stability, overflow performance, durability and pump temperatures during operation.

SUMMARY OF CLINICAL TESTS:

Clinical testing was not required to demonstrate the substantial equivalence of the Freestyle® double electric breast pump to its predicate device. However, published research studies are referenced support marketing claims.

CONCLUSION:

The differences between the Freestyle® double electric breast pump and its predicate devices do not introduce a new intended use and do not raise new issues of safety and effectiveness. Verification and Validation testing demonstrated that no adverse effects have been introduced by these differences and that the device performs as intended.

From the results of nonclinical testing described, Medela AG concludes that the Freestyle® double electric breast pump is substantially equivalent to the legally marketed predicate device.